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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/013,049	12/10/2001	Richard James Riehle	10086/2	2668

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/013,049

Applicant(s)

RIEHLE ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-21 and 35-38 is/are rejected.
- 7) ☒ Claim(s) 22-29, 31-34 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-21 and 35-38 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The additional step of contacting the composition with “at least one microorganism, or at least on enzyme located from the at least one microorganism, in an amount, and at a pH and temperature effective to dehalogenate residual quantities of organically bound halogen” is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 1-21 and 35-38 encompass a treatment process that includes treating a composition containing a wet strength polyamine-epihalohydrin resin comprising a solids content of at least 15 wt% with an enzymatic agent to inhibit, reduce or remove a CPD-forming species. The final amount of CPD-forming species remaining in the composition after the enzyme treatment is defined in terms of the “ACID TEST”. That is, the treated composition when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD.

Review of the originally filed disclosure includes 38 Examples.

Example 1 is drawn solely to the manufacture of a wet strength polyamine-epihalohydrin composition with a solids content of 21.08% and includes CPD-forming species.

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Example 2 is drawn to an enzymatic treatment of the composition of Example 1. The results of Example 2 do not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. See table 1.

Example 3 is drawn to a biodehalogenation treatment of the treated composition of Example 2. It is noted that the treated composition of Example 2 is diluted prior to treatment with the microorganisms. As shown in Table 1 the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”.

Example 4 is drawn to a diluted composition of Example 1. The starting composition has a solids content less than 15 wt%.

Example 5 is drawn to a comparison of a paper product using the treated compositions of Examples 3 and 4.

Examples 6-19 are drawn to enzyme treatments of high solids (at least 15 wt%) wet strength polyamine-epihalohydrin compositions. While a high solids composition was treated with the enzyme composition, the tabulated data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. See table 3.

Example 20 is drawn to a combined enzyme-biodehalogenation treatment method of a diluted (less than 15 wt%) starting composition. While the “ACID TEST” establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”, see table 4, the starting composition did not include a solids composition of at least 15 wt %.

Example 21 is similar to Example 20 but employs twice as much enzyme.

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Example 22 is similar to Examples 20 and 21. This example employs a different starting composition but the solids content is still less than 15 wt%.

Example 23 is drawn to biodehalogenation of a starting composition of at least 15 wt%.

Example 24 is drawn to a sequential enzyme-biodehalogenation treatment process with a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD", see table 11, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Example 25 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. While the "ACID TEST" establishes that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD", see table 12, the treatment process employed both an enzyme treatment and biodehalogenation treatment.

Examples 26-30 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 31 and 32 are drawn to an enzyme treatment of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD". See tables 21 and 22.

Examples 33 and 34 are limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

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Example 35 is drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. See tables 25 and 26.

Example 36 is limited to biodehalogenation of starting compositions of at least 15 wt% but do not involve an enzyme treatment as required of the instant claims.

Examples 37 and 38 are drawn to a combined enzyme-biodehalogenation process of a starting composition of at least 15 wt%. However, the resulting data does not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. See tables 28 and 29.

In summary, only Examples 3, 24 and 25 are drawn to treatment methods that treat a starting composition with a solids content of at least 15 wt% wherein the treatment method includes the claimed enzyme treatment and establishes that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. However, it is apparent to one of ordinary skill in the art that the biodehalogenation **step is critical to the invention** since each of these examples also included a biodehalogenation step as part of the treatment process that resulted in a treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”. Note the examples that where drawn solely to an enzyme treatment of a starting composition of at least 15 wt% did not establish that the treated composition “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”.

Allowable Subject Matter

3. Claims 22-29, 31-34 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

4. With respect to the rejection of Claims 1-21 and 35-38 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, Applicants argue (See pages 2-4 of the response filed 9/27/2006) that the rejection is improper because the instant specification does not include any language stating that a biodehalogenation step, or any additional step, is critical to practice the claimed invention. Applicants stress that the Examiner has only reviewed the examples and has not considered the entire specification when making his determination of criticality.

In response, while the instant specification does not explicitly recite that the biodehalogenation step is critical to practicing the claimed invention, for the reasons already of record, the Examiner maintains that the biodehalogenation step is critical to practicing the claimed invention. If the step is not critical, then the examples wherein a composition of at least 15 wt% is treated without the biodehalogenation step would have resulted in a composition with the properties required in the instant claims. The examples which correspond to these conditions do not show or establish that a composition with the claimed properties results with the composition is not also treated with the disclosed biodehalogenation step. In making this determination the Examiner has considered the entire disclosure and not just the examples.

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While the disclosure make certain broad statements, the examples clearly establish that when treated a composition of at least 15 wt%, a biodehalogenation step is required to obtain a product with the claimed properties. Note applicants even admit that compositions with greater than 15 wt% involve unpredictable results.

Applicants stress that page 15, line 27, to page 16, line 2, of the instant specification indicates that the enzyme treatment can be applied without further treatment.

In response, while this may be true, as evidenced by the examples discussed previously, when obtaining a treated product that includes the following claimed property “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD” a biodehalogenation step is required to provide a composition with this specifically claimed property. As evidenced by the other examples, the composition can be treated with the enzyme without further treatment, but the resulting composition does not have the claimed property “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD”.

Applicants finally argue that the additional treatment steps discussed by Applicants are merely optional and not critical to the practice of the claimed invention.

In response, as discussed immediately above, while this may be true, as evidenced by the examples discussed previously, when obtaining a treated product that includes the following claimed property “when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD” a biodehalogenation step is required to provide a composition with this specifically claimed property. As evidenced by the other examples, the composition can be treated with the enzyme without further treatment, but the resulting composition does not

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have the claimed property "when stored for 24 hours at 50°C, and a pH of about 1.0 releases less than about 100 ppm dry basis of CPD".

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB